Risk factors for the development of placebo adverse reactions in a multicenter clinical trial

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Abstract: In this report, we examine the potential risk factors for both the incidence and the number of placebo adverse reactions among patients who were enrolled in the placebo control group in a multicenter clinical trial (n = 491). Of the nine baseline covariates analyzed, only clinical center was significantly related to both the presence and the number of adverse reactions. Placebo group patients at clinical centers 5 and 7 were more than twice as likely to experience an adverse reaction than were patients at clinical center 1. This finding, in light of the intensive effort we made to standardize the methods for adverse reaction detection and management, points out the difficulty in controlling for the inherent differences in the characteristics of the patient populations and clinic personnel at the clinical centers in a multicenter trial, and reinforces the need to stratify by clinical center prior to randomization.